K042664

DEC - 8 2004

510(k) Summary
LPS Upper Extremity

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581

A. Contact Person:

Tiffani Rogers
Regulatory Affairs Associate
(574) 371-4927

B. Device Information:

Proprietary Name:	LPS Upper Extremity
Common Name:	Shoulder prosthesis; Elbow prosthesis
Classification Name and Regulatory Class:	Prosthesis, shoulder, non-constrained, metal/polymer cemented: Class II per 21 CFR §888.3650 Elbow joint metal/polymer constrained cemented prosthesis: Class II per 21 CFR §888.3150
Product Code:	87 KWT, 87 JDC

C. Indications for Use:

The LPS Upper Extremity is intended for use in replacement of the proximal, mid-shaft or intercalary portion, distal and/or total humerus. This system is especially designed for cases that require extensive resection and restoration. Specific diagnostic indications for use include:

- Primary bone neoplasnms (e.g., osteosarcomas, chondrosarcomas, Ewing's sarcomas) requiring extensive resection(s) and replacement(s) of the proximal and/or distal humerus;
- Metastatic bone disease and pathologic fractures with extensive bone loss or where other forms of treatment such as internal fixation are inadequate;
- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement of the proximal and/or distal humerus;
- Patients suffering from congential or acquired deformity, such as post-traumatic deformity and/or arthritis;
- Communited fractures of the proximal, distal and/or humeral shaft where forms of fixation are indadequate;
- Persistent humeral fracture non-union;
- Patients suffering from severe cuff tear arthropathy that does not respond to any conservative therapy or better alternative surgical treatment;
- Revision shoulder or elbow arthroplasty cases requiring extensive resection(s) and replacements of the proximal, distal or total humerus.

- Severe trauma requiring extensive resection and replacement

The LPS Upper Extremity components are for **CEMENTED USE ONLY**.

D. Device Description:

The LPS Upper Extremity components are designed for the replacement of the mid-shaft or intercalary portion of the humerus, proximal, distal and/or total humerus. Unlike primary shoulder and elbow systems, this system is used when the amount of resection and restoration is extreme (e.g. in oncology cases, end-stage revision). A total humeral replacement is possible in those cases where no part of the humerus can be salvaged.

E. Substantial Equivalence:

The substantial equivalence of the LPS Upper Extremity is substantiated by its similarity in indications for use, design, materials, sterilization and packaging to the Global Advantage Total Shoulder system (K992065, cleared July 12, 1999), the Biomet Orthopedic 3-piece Proximal Humeral Replacement System (K020045, cleared January 30, 2002), the Biomet Orthopaedic Discovery Elbow – Mosaic Distal Humeral Replacement System (K033280, cleared December 19, 2003) and the Acclaim Elbow, cleared as the DePuy Total Elbow (K992656, cleared November 05, 1999).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2004

Ms. Tiffani D. Rogers
Regulatory Affairs Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K042664
Trade/Device Name: LPS Upper Extremity
Regulation Numbers: 21 CFR 888.3150, 21 CFR 888.3650
Regulation Names: Elbow joint metal/polymer constrained cemented prosthesis,
Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JDC, KWT
Dated: September 23, 2004
Received: September 28, 2004

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

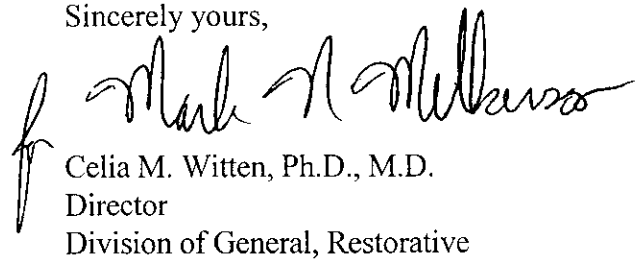
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042664
Device Name: **LPS Upper Extremity**

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- Severe trauma requiring extensive resection and replacement

The LPS Upper Extremity components are for **CEMENTED USE ONLY**.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhauser

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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